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09/716,146	11/17/2000	Christopher T. Boyle	6006-018	6734

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ART UNIT	**PAPER NUMBER**
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Please find below and/or attached an Office communication concerning this application or proceeding.

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/716,146
Filing Date: November 17, 2000
Appellant(s): BOYLE, CHRISTOPHER T.

J. Peter Paredes (Registration No.57,364)
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed September 28, 2006 appealing from the Office action mailed October 28, 2005.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is incorrect. A correct statement of the status of the claims is as follows:

Claims 1-15, 17-19, and 21-25 have been canceled.

Claims 16, 20, and 26-28 remain pending, rejected and on appeal.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is incorrect.

An amendment after final was filed. The amendment after final rejection filed on March 28, 2006 has not been entered.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is substantially correct. The changes are as follows:

Applicant has accidentally listed the grounds of rejection in the "status of claims" section of the brief. The grounds of rejection are as follows (corrections made in bold face):

Claims 16, 20, and 26-28 are finally rejected under 35 U.S.C. 102(e) as being anticipated by Brown, et al., U.S.Patent No. 6,071,305.

Claims 16, 26, and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Monaco et al., PCT Publication No. WO 94/18906.

Claims 16, 20, and 26-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Yan U.S. Patent No. 5,843,172.

Claims 16, **26, and 27** are rejected under 35 U.S.C. 102(b) as being anticipated by Buirge U.S. Patent No. 5,735,897.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

6,071,305	Brown et al.	06-2000
WO 94/18906	Monaco et al.	09-1994
5,843,172	Yan	12-1998
5,735,897	Buirge	04-1998

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 16, 20, and 26-28 are rejected under 35 U.S.C. 102(e) as being anticipated by Brown et al. (US 6,071,305, cited in previous office action). The examiner's interpretation of the "layers" in the Brown reference is also pointed out in Attachments 1-5. Referring to claim 16, Brown discloses an endoluminal stent (11, 40'', 111) comprising a plurality of structural elements (element 12 seen in figure 1, however having the structure, mesh or roving wire stents, each elongated member 12 being a filament or fiber which forms a mesh stent, disclosed in col.7, lines 34-40, that is, although Brown has shown a helical stent made of one structural element in fig.1, Brown also discloses use of a stent with multiple structural elements 12, wires/fibers/filaments, col.7, lines 34-40; or element seen in cross section fig.12 and disclosed in col.11, lines 50-61; or elements 112 in fig.18) forming a radially expandable cylindrical member, the structural elements are fabricated from metal (col.7, lines 12-19) having a wall thickness (thickness of wire/fiber/filaments, shown in fig.3-12 as the cross-sectional dimension), wherein the structural elements (member 12, or member shown in fig.12) are comprised of a base layer and a second layer covering the base layer (see arguments above and attachments 1-5), further comprising a void space (20) intermediate the base and second layers and enclosed therebetween and a plurality of pores (pores may be openings 22, 28, 54; col.6, lines 12-21 or alternatively pores may be pores in the porous stent material col.10, lines 36-38) passing through at least one of the base and second layers and communicating with the void space (20 or channel) and at least

one bioactive agent (23) retained within the void space (20 or channel) and elutable through the plurality of pores (22, 28, 54).

Regarding the claimed "layers" Brown's figures shown the claimed layers as so:

Brown has disclosed many embodiments having the layers as claimed. One embodiment is shown in figure 5 (see attachment 1), wherein one layer (seen in yellow) may be considered element 12'' and another layer (seen in red) may be considered 34 (it is noted to the applicant, that although the structural elements are claimed to be fabricated of metal, the "layers" are not required by the claim to be metal; that is the structural elements as a whole need only *comprise* metal and may include other materials as well), the void layer 20 being therebetween. Another embodiment is shown in figure 7 (see attachment 2), wherein one layer (seen in yellow) may be considered the outer perimeter of element 40, and an additional layer may be considered to be 44 (seen in green) or even 49 (seen in red), the void layer 20 therebetween. Also in figure 7 (see attachment 3), one layer (seen in yellow) may be considered the right side of outer perimeter, and a second layer (seen in green) may be on the left side of the outer perimeter (openings may exist in the layers, because the member is disclosed to be optionally made of porous metals), the void space 20 therebetween. Another embodiment in figure 8, (see attachment 3), shows a layer to be the outer perimeter (shown in yellow) and a second layer (shown in green) and void 20 therebetween. Figure 10 and 12 also show similar separate discrete layers (as applicant has argued are not present and is discussed below). The term "layer" is defined broadly by "a single thickness overlying a surface", and it is noted to the applicant a single thickness is not necessarily a constant thickness. Even so, Brown has shown such thicknesses in all of Brown's figures, and a square cavity in a square cross-sectional element (as disclosed by Brown; col.6,

lines 1-5) provides a single and even constant thicknesses anyhow. Brown's elements may be described at a unitary structure made up of many layers. One could call any particular thickness within Brown's element to be a "layer", see attachment 4 and attachment 5.

Referring to claim 20, Brown discloses a degradable plug (biodegradable matrix 27 extending into pore, as is seen in figs.3, 7, 9, and 12, see col.8 line 61-67 and col.9, lines 1-7; or membrane 34, 50, see col.9, lines 12-21, which is disclosed to made of the same materials are the biodegradable matrix, col.9, lines 1-5, 17-21; inherently prohibits release, until degradation, since the matrix is holding the agents) residing within the plurality of pores.

Referring to claim 26, Brown discloses a stent (10, 40'') having structural elements (member 12 in fig.1-10 or member shown in fig.12) comprising a material selected from the group claimed (col.7, lines 12-19).

Referring to claim 27, Brown discloses a bioactive or active agent (23) selected from the group claimed (col.5, lines 1-27).

Referring to claim 28, Brown discloses a void space (20 or channel in fig.12) comprising a plurality of independent internal cavities along the length of the structural elements (a plurality of cavities are shown in fig.9, 10, and 18; and cavities are shown to be intermittent in fig.18).

Claims 16, 26, and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Monaco (WO 94/18906, cited previously). See figures 8-10 and respective portions of the specification. Monaco discloses a plurality of structural elements (each layer may be considered a different structural element) forming a radially expandable (Monaco discloses use of titanium or stainless steel, two metals disclosed/admitted by *applicant* to be expandable; also as evidence,

Brown 6,071,305 discloses an expandable stent made of such titanium's and stainless steel, col.2 lines 53-55, col.7 lines 10-22, these materials are expandable by evidence of both the applicant and a prior art reference) cylinder having a wall thickness, the elements fabricated of metal (pg.8, lines 10-12) and comprising a base layer (housing 105) and a second layer (housing 110), further a void space (130) inbetween the two and a plurality of pores (160) passing through one of the layers (both 105 and 110) and a bioactive agent (cells secreting agent or 135; pg.7, lines 30-32; pg.21, lines 22-25) retained in the void space for release through the pores.

Claims 16, 20, and 26-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Yan (US 5,843,172, cited previously). See figures 6, 11, 12, and respective portions of the specification. Yan discloses an endoluminal stent (104; fig.1, 9) having a wall thickness and metallic structural members comprising a base layer (middle region layer in fig.12; or layer 44 in fig.6) and second layer (outer surface region layers in fig.12; or layer 41 in fig.6), and a void space (larger pores located near the center 52) intermediate the layers and a plurality of openings (smaller pores near surface 54) connecting the cavities to the stents exterior (col.7, lines 1-16; col.8, lines 45-58), and bioactive agents (therapeutic agent) disposed within the cavities.

Yan discloses the tubular member or structural body comprising a material selected from the group claimed (col.4, lines 32-39). Yan discloses a bioactive or active agent selected from the group claimed (col.5, lines 1-30). Yan discloses a degradable plug (coating or matrix 100; fig.11, 12; col.9, lines 15-40) residing within the at least one of the openings.

Claims 16, 26, and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Buirge (US 5,735,897). Buirge discloses an endoluminal stent (10; fig.1) having a wall thickness and metallic (discloses polymeric or other materials, col.2, lines 65-67; such as metals, col.5, lines 38-46) structural elements (structural elements may be considered to be the separate layers, or the separate fibers within one layer) comprising a base layer (12) and second layer (16), and a void space (location at 14; area between 12 and 16 filled with drug/matrix 14) intermediate the layers and a plurality of openings (layer 12 is porous; col.2, lines 53-65) connecting the cavities to the stents exterior, and bioactive agents (therapeutics/drug matrix including gel; col.4, lines 8-27) disposed within the cavities.

(10) Response to Argument

a. Applicant has argued the meaning of the term "layer". The applicant argues that the term "layer" is defined in their specification by the method of fabrication, a deposition process. The examiner disagrees. First, ***if*** the examiner were to assume the term layer in the claim required a deposition process by its meaning, this would make the claim a product by process claim. Layer would then be considered a method of fabrication or a process step, which is irrelevant in a product claim, see MPEP 2113. Attention will be given to the *final end product* only, and the end product of Brown has the "layers" as much as the applicant has layers. Second, the term "layer" has not been defined as a *definition/meaning* in the applicant's specification, therefore, "layer" has been given its plain meaning. A "layer" may be considered a thickness of material spread over a surface, or a piece of clothing placed on another piece of clothing, for example. A layer need not be flat/planar nor it need be a constant thickness as the

applicant has repeatedly argued. Nonetheless, applied references indeed include embodiments wherein structural members are planar/flat, and are of a constant thickness (see rejection above).

i). Applicant has argued that the two layers are required to be metal. The examiner disagrees. The claims as written, can be interpreted that the structural elements are metal or comprise metal, however the layers need not be made of metal at all. Either way, the applied references disclose embodiments wherein the two layers are both metal (see rejection above).

ii). Applicants have argued that the claim requires a vacuum deposition process. The examiner disagrees. No such method is claimed and "layer" does not require a deposition process, as a layer may be present by other methods of fabrication and is a ***structure*** in form, not a method. The end product (whether deposited or not-although this is completely irrelevant since deposition is not claimed) is the same and is examined based on its structure only, which the applied references have the same end product as the applicants. The applicant has argued that deposition processes form different structures than other processes, since heterogeneities may be controlled in the material during deposition. Although heterogeneities ***may*** be controlled during deposition, they ***need not*** be controlled. Further, it is not claimed that they are controlled, what parameter or amount is controlled, nor are any particular properties claimed, therefore another method of fabrication is capable of forming the "layers" claimed. Applicant repeatedly argues a deposition process. It is reminded to the applicant that the claims are product claims, no weight is given to the method of production, only to the structure of the end product. Deposition is not even claimed in the first place and the examiner is unclear why applicant is strongly arguing this topic. Applicant is attempting to argue that they are claiming only a product, however at the same time, a deposition process need be examined into the term layer (therefore,

bringing a method step into the claim, product by process), theses two arguments being very contradicting.

b. The applicant has argued that Brown does not disclose layers that are of a single constant thickness and layers made of metal. It was noted above, that "layer" need not be a single constant thickness, nor a planar flat thickness, and the layers are not required by the claim to be metal. Even if "layer" did require a constant and flat thickness, and the two layers were required to be made of metal, Brown discloses such embodiments. Multiple embodiments of Brown are shown in the attachments that read on the claims, some of which are a constant thickness (see fig.7/attachment 3; a square cavity in a square cross-sectional element as disclosed by Brown; col.6, lines 1-5 provides a single constant thicknesses), flat thickness (a square cavity in a square cross-sectional element as disclosed by Brown; col.6, lines 1-5, col.8, lines 23-26, provides a flat/planar thicknesses), and metal layers (see fig.7/attachment 3; Brown's elements may be described at a unitary structure made up of many layers. One could call any particular thickness within Brown's element to be a "layer", see attachment 4 and attachment 5). Other embodiments of Brown that are believed by the examiner to have the claimed layers are seen in the remaining attachments as examples and specification as noted in the above rejection. The applicant also argues that Brown's embodiments do not have second layers that "cover" and void layers that are not "intermediate". The examiner disagrees. Covering layers and intermediate void spaces are clearly shown in the drawings and further pointed out in the attachments.

i). The applicant argues that Brown fails to disclose a degradable plug residing within the pores. The examiner disagrees. The cavities are filled with drugs and inherently will fill the

pores as well, due to the method of production which entails sloughing off excess drug. Further, several figures are shown with the drug extending into the pores (see fig.3, 9, and 12).

ii). The applicants have not argued claims 26-27 separately with respect to Brown.

iii). The applicants have argued that Brown does not disclose independent internal cavities. The examiner disagrees. As disclosed by Brown, multiple structural elements 12 may be configured to form a mesh stent (col.7, lines 34-39). Thus, each structural element 12, at least has its own independent cavity, thus a stent having multiple structural elements and multiple cavities is present. Further, figures 9, 10, and 18 show examples of how multiple independent cavities may be incorporated into one structural element 12. The main structural element 12 is used for all embodiments, inherently the different features of element 12 may be combined. Further, Brown has shown cavities extending the entire length of structural elements (12; see fig.2), however has disclosed that they may or may not need extend the entire length, giving both options for use.

To sum up the Examiner's position of the Brown rejection:

Applicant has again argued that Brown does not anticipate structural elements having separate layers, specifically, that Brown does not disclose a void space between two layers. The examiner disagrees. Brown has disclosed many embodiments having the layers as claimed. One embodiment is shown in figure 5 (see attachment 1), wherein one layer (seen in yellow) may be considered element 12'' and another layer (seen in red) may be considered 34 (it is noted to the applicant, that although the structural elements are claimed to be fabricated of metal, the "layers" are not required by the claim to be metal; that is the structural elements as a whole need only *comprise* metal and may include other materials as well), the void layer 20 being therebetween.

Another embodiment is shown in figure 7 (see attachment 2), wherein one layer (seen in yellow) may be considered the outer perimeter of element 40, and an additional layer may be considered to be 44 (seen in green) or even 49 (seen in red), the void layer 20 therebetween. Also in figure 7 (see attachment 3), one layer (seen in yellow) may be considered the right side of outer perimeter, and a second layer (seen in green) may be on the left side of the outer perimeter (openings may exist in the layers, because the member is disclosed to be optionally made of porous metals), the void space 20 therebetween. Another embodiment in figure 8, (see attachment 3), shows a layer to be the outer perimeter (shown in yellow) and a second layer (shown in green) and void 20 therebetween. Figure 10 and 12 also show similar separate discrete layers (as applicant has argued are not present and is discussed below). The term "layer" is defined broadly by "a single thickness overlying a surface", and it is noted to the applicant a single thickness is not necessarily a constant thickness. Even so, Brown has shown such thicknesses in all of Brown's figures, and a square cavity in a square cross-sectional element (as disclosed by Brown) provides a single and even constant thicknesses anyhow. The applicant has also argued that Brown does not disclose layers that are separate and discrete (first of all, the applicant has not claimed *discrete* layers), but instead are unitary. **The examiners position is that the applicant themselves does not have separate *discrete* layers. The applicant deposits layer upon layer during the fabrication process, in order to make a unitary end product. The unitary end product having the same structure as Brown.** Therefore, any section defined by two parallel longitudinal planes of Browns structural element may be considered to be a layer. The applicant even discloses the use of other fabrication processes besides deposition to arrive at the final end product, some of which do NOT require

the use of layers. Brown may not use a deposition process to form the final structure, and may not deposit layer upon layer of material, Brown does however have an end product the same as the applicants. Whether Brown uses laser treatment or deposition to arrive at the final device, the same final product device results. "Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227, USPQ 964, 966 (Fed. Cir. 1985), see MPEP 2113. It is futher noted, that **the applicant has not specifically defined the term layer in the specification**. That is, in the scope that the applicant has described, "layer" in their specification, Brown in this case, also has such layers, Brown's elements may be described at a unitary structure made up of many layers. One could call any particular thickness within Brown's element to be a "layer", see attachment 4 and attachment 5.

The applicant has additionally argued that their invention is not only discretely layered, but also unitary as well. It is unclear how the applicant may have both discrete layers and a single unitary structure at the same time. Nonetheless, Brown's stent structure is believe to be disclosed and shown to be the same structure as the applicant's stent, therefore, if the applicant believes their own device to be layered and unitary at the same time, the same can be said for the Brown stent.

The applicant has also argued that some of the embodiments of Brown comprise a polymer, and are not metal. The examiner disagrees. The applicant has claimed that the

structural elements are fabricated from metal. That is, they may be fabricated by metal and a polymer, since they are not limited to *only* metal. Brown's elements comprise metal and are believed to read on the claims. It is noted to the applicant, that the structural elements are claimed to comprise metal, however the first *and* second layers are not disclosed to be made solely of metal. **Even if both layers were required to be made of metal, Brown has shown several embodiments wherein the interpreted "layers" are both metal (see attachment 2-5).**

c. The applicant has argued that Monaco does not disclose a stent. First, a stent is defined in its plain meaning structurally as simply a tubular object, capable of holding open a vessel in the body (the capable language clearly being intended use, therefore, only a generally tubular object is required). Monaco clearly has shown a tubular object, see for example, figure 8. Monaco discloses generally tubular object for placement in the body that is capable of being placed within a vessel. Applicant has argued that their stent has a different thickness, however this is an irrelevant argument, a thickness is NOT claimed, and further, vessels may have a variety of sizes in diameter, ranging from small capillaries to large vessels such as the aortic vessel. A thickness further does not determine whether a tube is capable of fitting within a vessel, the diameter does. The applicant argues Moraco does not claim a single constant thickness. The examiner disagrees. First, a constant thickness is not claimed. Second, Moraco does disclose a thickness that may be constant (see fig.8). The applicant further argues that Moraco's device is not radially expandable. The examiner disagrees. Moraco clearly discloses use of titanium's and stainless steels (pg.8), both of which are know in the art to be expandable (see as evidence, Brown 6,071,305 discloses an expandable stent made of such titanium's and stainless steel, col.2 lines 53-55, col.7 lines 10-22), further are inherent properties of such

materials, and additionally are admitted by applicant in the specification to be examples of expandable materials (see applicants specification and claims). Further, such materials are considered radially expand*able*, since they may expand upon force.

i). Applicant have not argued claims 26-27 with respect to Monaco.

d. The applicant has argued that Yan does not disclose several layers of a single constant thickness. The examiner disagrees. First, a constant thickness is not required by the claim, as the applicant is attempted to argue. Second, Yan discloses several layers, see above rejection. Clearly the stent of Yan is seen split into several layers, shaded and non-shaded layers, see clearly in fig.12 for example. A void space, may be considered to be one pore in the center of Yan's stent structural element, which is as shown, enclosed between the two layers.

i). The applicant has argued Yan does not disclose a degradable plug with the openings. The examiner disagrees. Yan discloses coatings applied to a metallic stent, inherently the coating will seep into the openings, since pressure must be applied to place the coating on the stent. It would be nearly impossible to apply a coating to a porous surface so that the coating remained bubbled up above each individual pore/opening. Yan discloses loading the cavities and coating the surface with a degradable plug (coating or matrix, col.9, 1-20) by methods (col.9, lines 47-50) that would inherently provide the plug positioned within the openings/pores.

ii). The applicant has not argued claims 26-27 with respect to Yan.

e. The applicant has argued that Buirge does not disclose a void space. The examiner disagrees. Buirge clearly discloses a void space located at 14, or located between first (12) and second (14) layer, that comprises a drug/agent/matrix (composition is 14, however 14 points to the *location* of void space which is filled with composition 14). It is noted to the applicant, that

the applicant's "void space" is not void either, it is filled with a drug/matrix composition, same as Buirge's. Therefore, Buirge has as much of a "void space" as the applicant does.

i). The applicant has not argued claims 26-27 with respect to Buirge.

All rejection made in the final office action are believed by the examiner to be proper and have been maintained for the reasons above.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Cheryl Miller

Conferees:

for
Corrine McDermott

Angela Sykes

Attachment #1 (marked up)

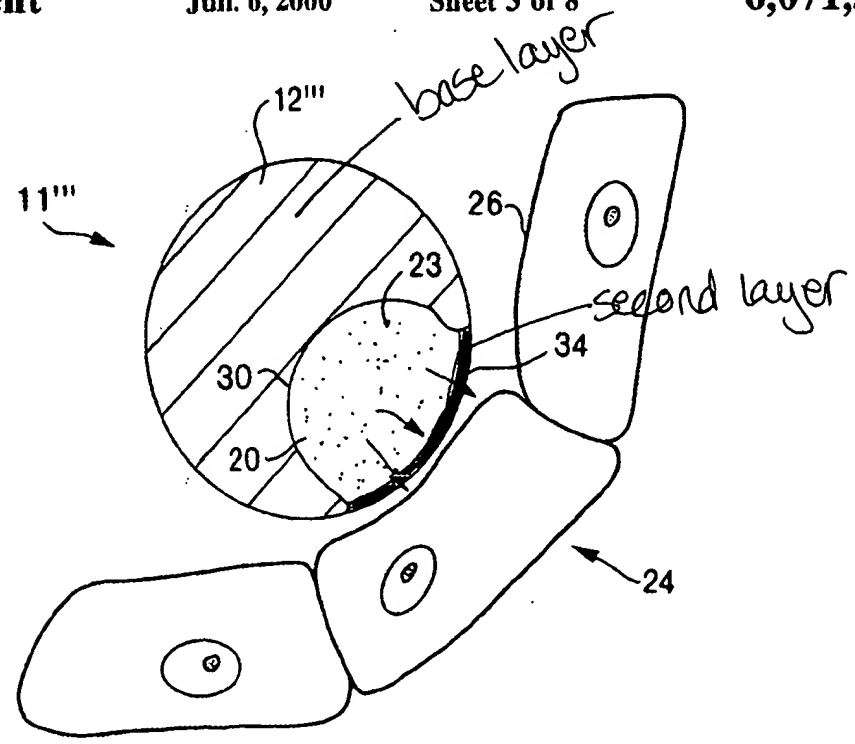

FIG. 5

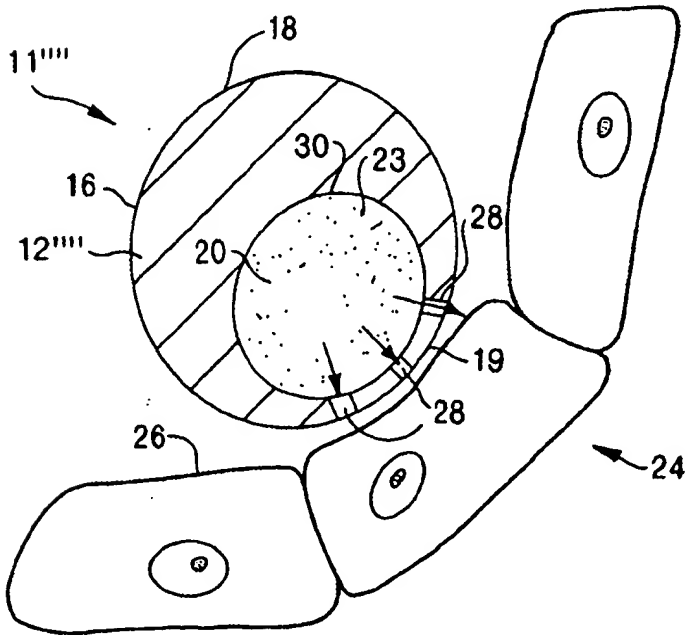

FIG. 6

Attachment #2 (marked up)

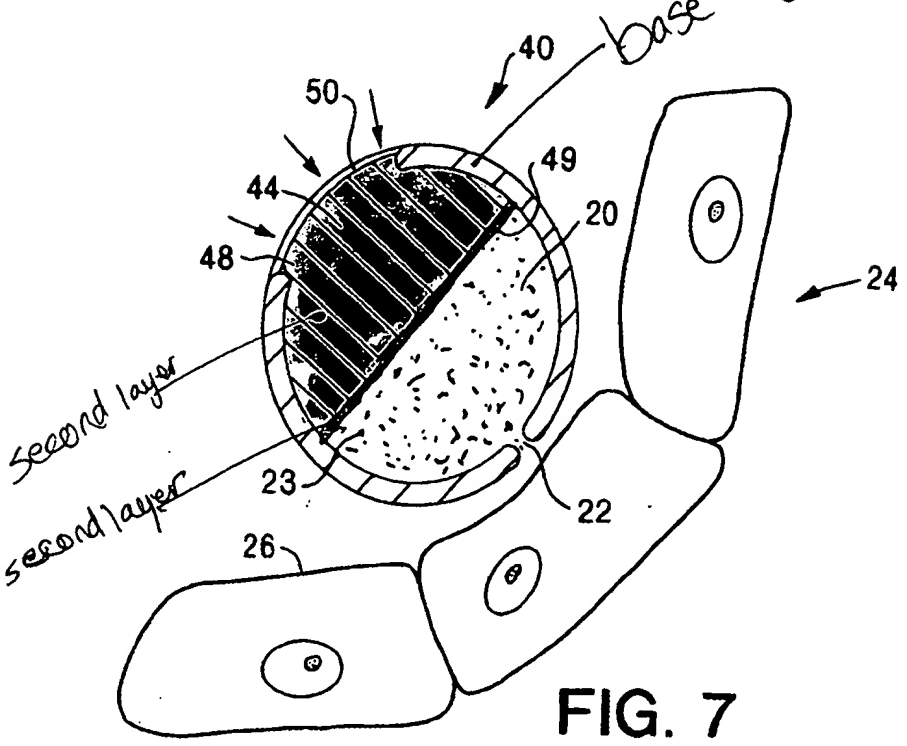

FIG. 7

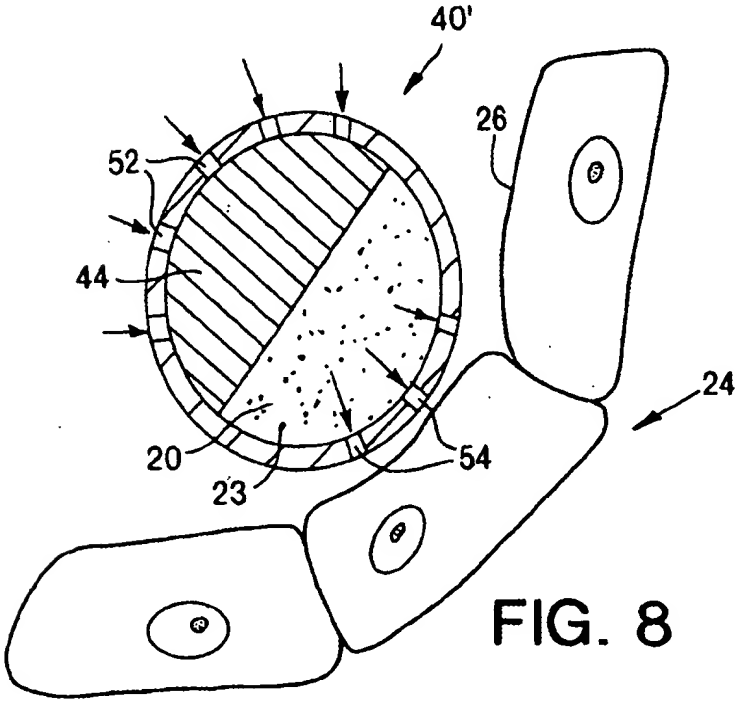

FIG. 8

Attachment #3 (marked up)

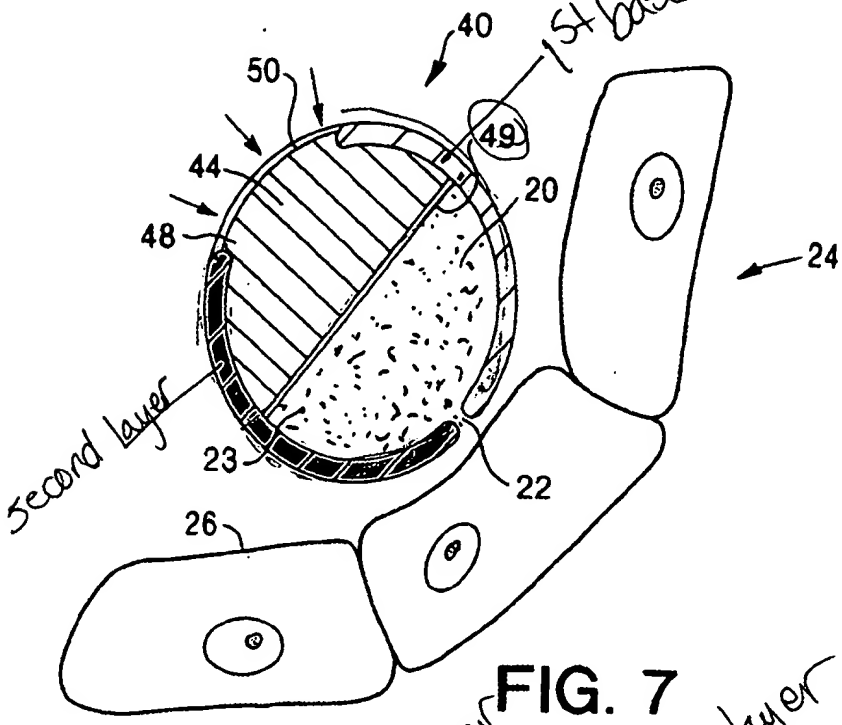

FIG. 7

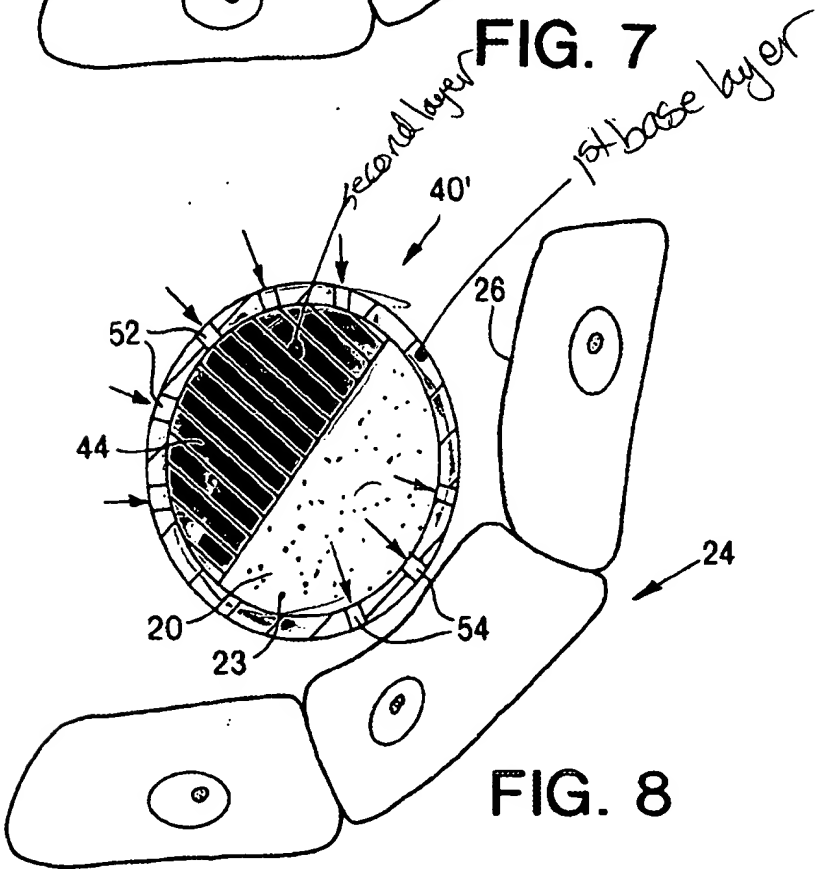

FIG. 8

Attachment #4 (markedup)

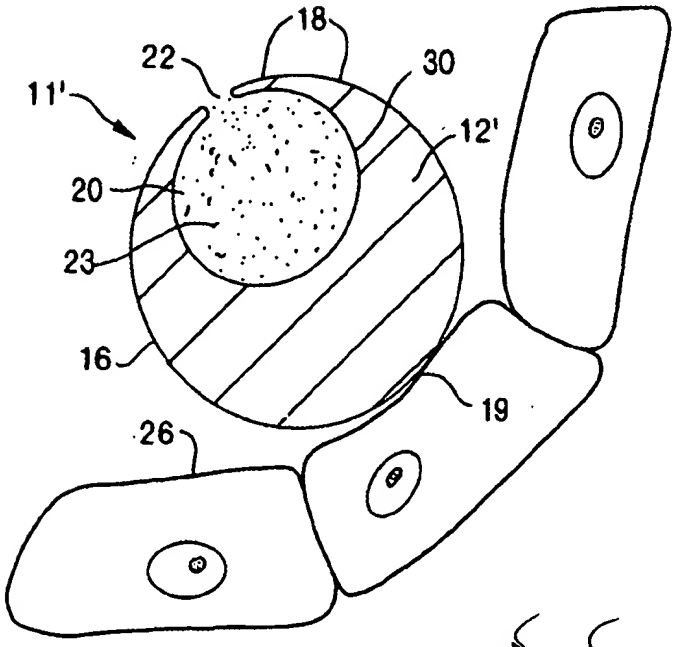

FIG. 3

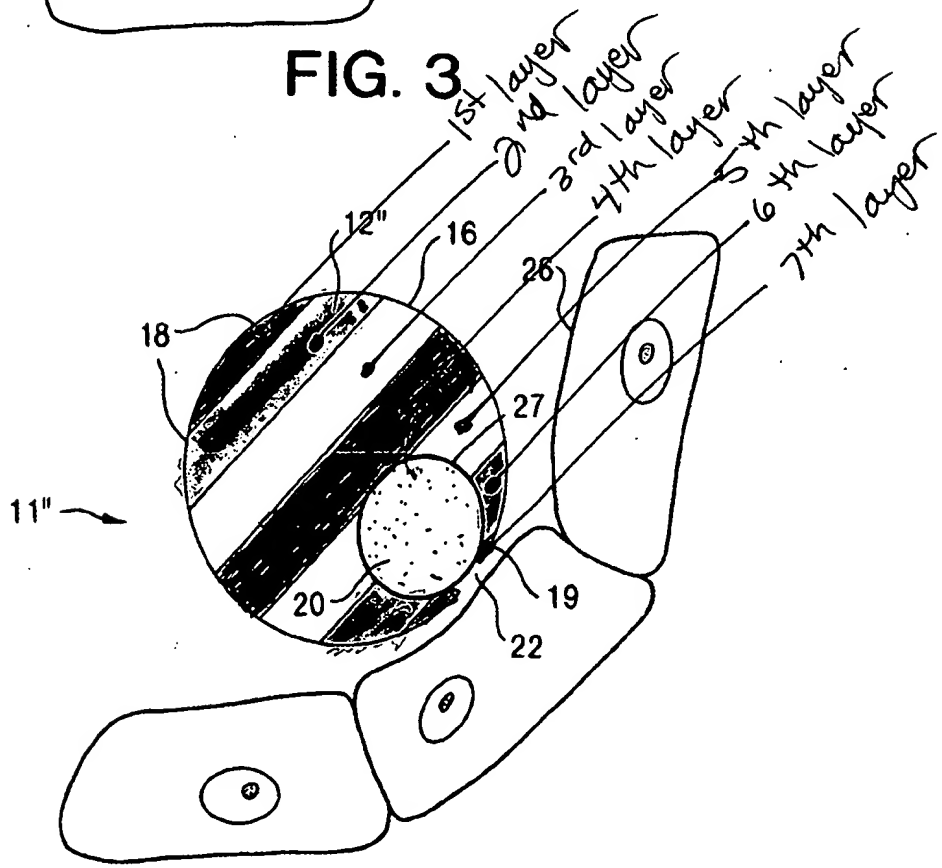

FIG. 4

Attachment #5 (marked up)

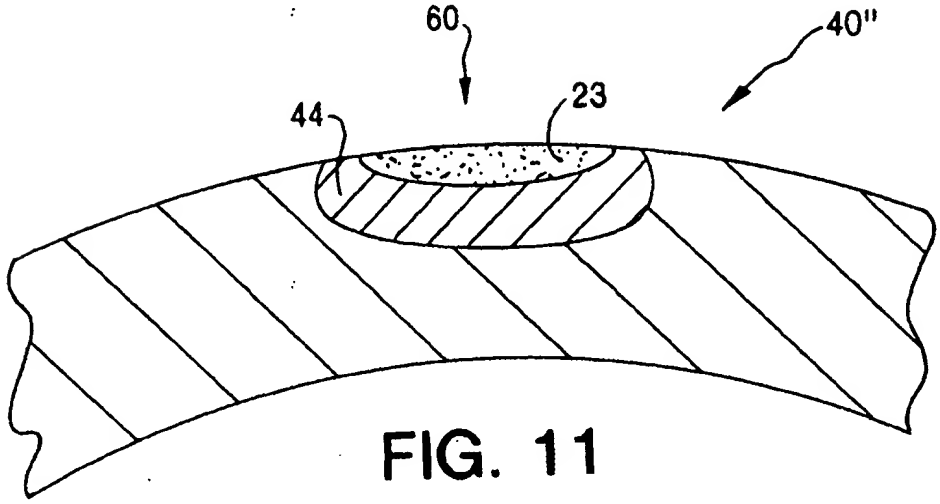

FIG. 11

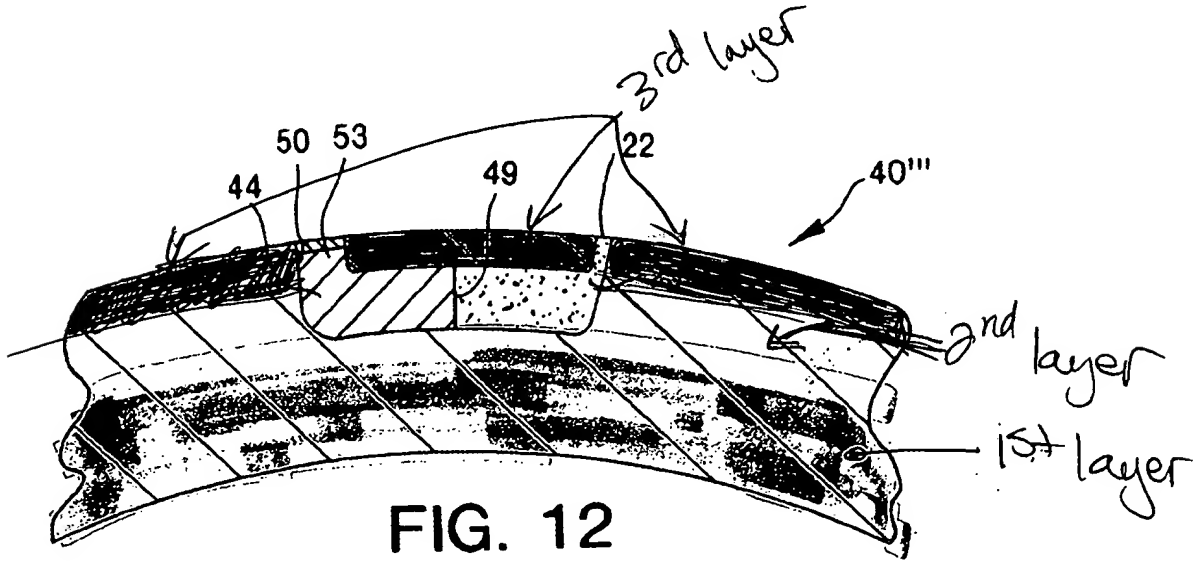

FIG. 12